REMARKS

This amendment is responsive to the Office Action dated August 16, 2005. Applicant has amended claims 1, 14, 27, 28, 31, 32 and 34, and canceled claims 15, 29, 30, and 33. Claims 1–14, 16-28, 31, 32, and 34–37 are pending.

Claim Rejections Under 35 U.S.C. § 102

In the Office Action, the Examiner rejected claims 1–11, 14–16, 19, 20, 22, 23, 27, 28, 30, 32 and 34–37 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,251,063 to Silverman et al. (Silverman). Applicant respectfully traverses these rejections to the extent such rejections may be considered applicable to the amended claims. Silverman fails to disclose each and every feature of the claimed invention, as required by 35 U.S.C. § 102(b), and provides no teaching that would have suggested the desirability of modification to include such features.

For example, Silverman fails to teach or suggest a method of implanting a bulking device beneath the mucosa in the lower esophagus, comprising puncturing the mucosa, enlarging the puncture, and introducing a bulking device through the enlarged puncture, as recited by Applicant's independent claims 1 and 34 as amended. As another example, Silverman fails to disclose or suggest a method of treating a condition in the lower esophagus that comprises positioning an expandable hydrogel bulking device within a pocket created beneath the mucosa in the lower esophagus, as required by Applicant's independent claim 14 as amended. Silverman also fails to teach or suggest using a cutting tool to create a tunnel through the mucosa and applying a force to explant a solid bulking device through the tunnel, as recited by Applicant's independent claim 27 as amended.

Claims 1-11 and 34-37

With regard to independent claims 1 and 34, the Examiner stated that Silverman teaches "enlarging the puncture," and further teaches "a method of implanting the bulking device, wherein the puncture enlarging step comprises introducing a dilator (balloon) through the puncture." However, the cited passage of Silverman describes a method of removing an implant, and does not address implanting a bulking device through an enlarged puncture, as required by independent claims 1 and 34. In particular, Silverman states at col. 19, ll. 20–34:

> The implants of the invention can be removed for reversing the procedure of the invention. . . . The treatment of the invention can also be reversed by expanding the augmented or coapted region created by the implants . . . such as by use of a balloon or bougie. (emphasis added).

This passage of Silverman describes a method of removing an implant in which the region created by the implants, not a puncture for introducing an implant, is expanded. Contrary to the Examiner's assertion, Silverman makes no mention of puncturing the mucosa, enlarging the puncture, and introducing a bulking device through the enlarged puncture, as recited in Applicant's independent claims 1 and 34 as amended.

In addition to failing to teach enlarging a puncture, Silverman provides no motivation to enlarge a puncture. Silverman describes injecting an augmenting solution into the esophageal mucosa using a needle. (Col. 15, ll. 60–67) The augmenting solution precipitates or forms a solid after it is injected into the mucosa. (Col. 16, ll. 10–15). Since the augmenting solution is a solution introduced by injection, there is no reason for the needle puncture to be enlarged for introducing the augmenting solution. Furthermore, for these reasons Silverman certainly fails to even suggest enlarging a puncture by introducing a dilator through the puncture, as recited by dependent claim 11.

Claims 14–16, 19, 20, 22 and 23

Silverman also fails to teach or suggest a method of treating a condition in the lower esophagus that comprises positioning an expandable hydrogel bulking device within a pocket created beneath the mucosa in the lower esophagus, as required by Applicant's independent claim 14 as amended. The Examiner makes two arguments relevant to this requirement of amended claim 14. First, the Examiner argues that Silverman discloses hydrogel, which is inherently expandable in response to exposure to fluid. Second the Examiner argues that certain portions of Silverman (FIGS. 7 and 8, col. 19, ll. 31-34) depict or describe an implant that expands. Applicant respectfully suggests that both of these arguments are incorrect.

First, Applicant fails to see how the disclosure within Silverman cited by the Examiner (col. 9, ll. 54-66) supports the Examiner's inherency argument. Silverman teaches bulking by injection of an augmenting solution that may include 2.5 to 8.0 percent weight of a biocompatible polymer, such as a hydrogel. (Col. 9, ll. 35-66). As described elsewhere in

Silverman, the hydrogel may precipitate to form a solid implant. (E.g., col. 9, ll. 9-34). In general, whether or how much a hydrogel expands when exposed to fluids will depend on whether or how much the hydrogel is hydrated prior to exposure. Silverman does not suggest that the hydrogel absorbs fluid or expands upon implantation or precipitation.

Inherency requires that one skilled in the art would **necessarily** understand the applied reference to include the missing disclosure.[1] The **mere possibility** that one skilled in the art might interpret a general disclosure as including undisclosed features is insufficient to show inherency.[2] Because hydrogel may or may not expand when exposed to fluid, e.g., implanted, based on the degree of prior hydration, and because Silverman does not provide any disclosure that suggests whether the hydrogels described therein are hydrated prior to implantation, or absorb fluid or subsequent to implantation, one of ordinary skill in the art **would not necessarily** have understood an expandable hydrogel bulking device to be included within the disclosure of Silverman.

Second, Applicant fails to see how FIGS. 7 and 8 of Silverman provide any suggestion of an expandable bulking device. The implant 228 illustrated in FIGS. 7 and 8 appears to be the same size in both of the figures. Further, FIG. 7 appears to illustrate implant 228 during injection of the augmenting solution, while FIG. 8 illustrates implant 228 after injection is complete. In other words, if the sizes of implant 228 in FIGS. 7 and 8 are different, it appears to be because the figures illustrate different points during injection of the implant, rather than expansion of the implant.

Claims 27, 28, 30 and 32

Silverman also fails to teach or suggest using a cutting tool to create a tunnel through the mucosa, and applying a force to explant the solid bulking device through the tunnel, as recited by Applicant's independent claim 27 as amended. Silverman describes dissolving or partially dissolving an implant, and then removing the "reformed augmenting solution" with a needle passage. In this embodiment, the implant is removed while in the form of a solution, not a solid. Silverman further describes alternatively incising the mucosal layer "to release the implant

[1] *See Finnigan Corp. v. ITC*, 51 USPQ2d 1001, 1009 (Fed. Cir. 1999) (emphasis added).
[2] *See id.* (emphasis added).

therein from wall 193." (Col. 19, ll. 28–30). However, in no manner does Silverman teach explanting a solid bulking device through a tunnel created by a cutting tool by applying a force.

For at least the above reasons, the Silverman reference fails to disclose all of the features set forth in independent claims 1, 14, 27, 34, and therefore does not support a prima facie case of anticipation with respect to the claimed invention. The claims dependent on independent claims 1, 14, 27, 34, i.e., claims 2–13, 16–26, 28, 31, 32, and 35–37, incorporate all of the limitations of these base claims, and therefore are patentable for the reasons expressed above.

In order to support an anticipation rejection under 35 U.S.C. § 102(b), it is well established that a prior art reference must disclose each and every element of a claim. This well known rule of law is commonly referred to as the "all-elements rule."[3] If a prior art reference fails to disclose any element of a claim, then rejection under 35 U.S.C. § 102(b) is improper. [4]

As detailed above, Silverman fails to disclose each and every limitation set forth in claims 1–11, 14, 16, 19, 20, 22, 23, 27, 28, 32 and 34–47. For at least this reason, the Examiner has failed to establish a prima facie case for anticipation of Applicant's claims 1–11, 14, 16, 19, 20, 22, 23, 27, 28, 32 and 34–47 under 35 U.S.C. § 102(b). Withdrawal of these rejections is requested.

Claim Rejections Under 35 U.S.C. § 103

In the Office Action, the Examiner rejected claims 17, 18, 21, 24–26, 29, 31 and 33 under 35 U.S.C. § 103(a) as being unpatentable over Silverman, and rejected claims 12 and 13 under 35 U.S.C. § 103(a) as being unpatentable over Silverman in view of U.S. Patent No. 4,473,067 to Schiff (Schiff). Applicant respectfully traverses these rejections to the extent such rejections may be considered applicable to the claims as amended. The applied references fail to disclose or suggest the inventions defined by Applicant's claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed invention.

---

[3] *See Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 231 USPQ 81 (CAFC 1986) ("it is axiomatic that for prior art to anticipate under 102 it has to meet every element of the claimed invention").
[4] *Id. See also Lewmar Marine, Inc. v. Barient, Inc.* 827 F.2d 744, 3 USPQ2d 1766 (CAFC 1987); *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (CAFC 1990); *C.R. Bard, Inc. v. MP Systems, Inc.*, 157 F.3d 1340, 48 USPQ2d 1225

Initially Applicant notes that neither Silverman nor Schiff provide any teaching that would overcome the deficiencies of Silverman with respect to the requirements Applicant's independent claims discussed above. For at least this reason, the Examiner has failed to establish a prima facie case for non-patentability of Applicant's claims 12, 13, 17, 18, 21, 24–26, 29, 31 and 33 under 35 U.S.C. § 103(a), and the rejections of each of these claims should be withdrawn. Moreover, the applied references, either alone or in combination, fail to teach or suggest a number of the requirements recited in these claims.

Claims 17, 18, 21, 24–26, 29, 31 and 33

In the Office Action, the Examiner acknowledged that the features of Applicant's claims 17 and 18 are not disclosed or suggested by Silverman. Nonetheless, the Examiner concluded that it would have been obvious to one having ordinary skill in the art at the time of Applicant's invention to determine through routine experimentation to modify the system described by Silverman to include a bulking device having a diameter prior to implantation within the range of from about 0.2 mm to about 5 mm, or having a cross section prior to implantation of no more than about 2.5 mm. Applicant respectfully disagrees with this conclusion.

Even if an appropriate diameter and cross section for a bulking device prior to implantation could be determined through routine experimentation, this determination and the Silverman disclosure would not lead a person of ordinary skill in the art to modify Silverman to arrive at Applicant's claimed invention. As discussed above, Silverman describes injecting an augmenting solution into the esophageal mucosa, after which the augmenting solution precipitates or forms a solid implant. Since the augmenting solution is in the form of a solution prior to being injected, the augmenting solution would in no manner have a diameter or cross section "prior to implantation." Thus, one of skill in the art would have no motivation to determine optimal dimensions of the augmenting solution taught by Silverman. Further, one of skill in the art would have no motivation to perform experimentation to determine optimal dimensions of a solid bulking device, since such a bulking device could not be injected using Silverman's device.

(CAFC 1998); *Oney v. Ratliff*, 182 F.3d 893, 51 USPQ2d 1697 (CAFC 1999); *Apple Computer, Inc. v. Articulate Systems, Inc.*, 234 F.3d 14, 57 USPQ2d 1057 (CAFC 2000).

With respect to claims 21, 24–26, 29, 31, and 33, the Examiner similarly acknowledged that the features of these claims are not disclosed or suggested by Silverman. The Examiner cited no teaching of these features within the other identified references, or elsewhere within the prior art. Nonetheless, the Examiner stated that "it has generally been held to be within the skill level of the art to substitute alternative ways for explanting implants from the tissues or organs." However, the Examiner failed to point to any authority for this statement. Even if one of ordinary skill in the art would have been motivated to modify the Silverman system to explant a bulking device using suction, a laser, an energy source, or by cutting the bulking device in pieces, Silverman lacks numerous features of claims 14 and 27 as explained above, upon which 21, 24–26, and 31 respectively depend. Applicant has canceled claims 29 and 33.

Claims 12 and 13

Claims 12 and 13 are patentable for the same reasons stated above for independent claim 1 and dependent claim 11; namely, because the Silverman reference lacks the basic teachings attributed to it by the Examiner. Moreover, one skilled in the art would have had no motivation to look from Silverman to Schiff for any modifications; nor does Schiff provide any teaching sufficient to cure the basic deficiencies already evident in Silverman.

For example, claim 12 recites a dilator, introduced through the puncture to enlarge the puncture, which removably carries an introducer sheath. Claim 13 recites removing the dilator from the introducer sheath and introducing the bulking device through the introducer sheath and into the pocket. As discussed above, Silverman fails to teach or suggest enlarging a puncture by introducing a dilator through the puncture, recited by claim 11, upon which claims 12 and 13 depend. The Examiner correctly recognized that Silverman fails to teach implanting a bulking device, wherein the dilator removably carries an introducer sheath, and the steps of removing the dilator from the introducer sheath and introducing the bulking device through the introducer sheath and into the pocket. Nonetheless, the Examiner stated that "it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the steps of Silverman . . . by including an introducer sheath as taught by Schiff." Since Silverman does not teach introducing a dilator to enlarge a puncture or introducing a solid bulking device, as discussed above, it is difficult to see how it would have been obvious to modify Silverman in light of

Schiff to result in removing a dilator from an introducer sheath and introducing a solid bulking device using the introducer sheath. Further, Schiff is not related to gastroesophageal procedures, but instead is directed to introducing intra-aortic balloons into the femoral artery for assisting the heart. One of ordinary skill in the art would not be motivated to modify Silverman in light of Schiff, and even if this were so, such modification would not result in the features required by Applicant's claims 12 and 13.

For at least these reasons, the Examiner has failed to establish a prima facie case for non-patentability of Applicant's claims 12, 13, 17, 18, 21, 24–26, 31 under 35 U.S.C. § 103(a). Withdrawal of these rejections is requested.

CONCLUSION

All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims. Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

Date: 11/16/05

By: _____

SHUMAKER & SIEFFERT, P.A.
8425 Seasons Parkway, Suite 105
St. Paul, Minnesota 55125
Telephone: 651.735.1100
Facsimile: 651.735.1102

Name: Jason D. Kelly
Reg. No.: 54,213